ORI Newsletter

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Planning Meeting Held For Developing Research Agenda

Representatives from scientific societies, professional associations, and funding agencies met at ORI on June 3 to begin discussing the development of a research agenda on scientific misconduct and research integrity.

Attendees represented the Association of American Medical Colleges, the Federation of American Societies for Experimental Biology, the American Association for the Advancement of Science, the National Institutes of Health, and the National Science Foundation.

Besides creation of a research agenda, three other developments are needed to create an "invisible college" focused on scientific misconduct and research integrity: formation of a research group, establishment of databases, and cultivation of funding sources.

ORI plans to ask the Institute for Scientific Information to assist in the identification of a research group by providing a topical report on the scientific misconduct literature that will list papers, authors, institutions, and journals. Citations to that literature will also be identified by authors, institutions, and journals.

ORI has already communicated some data to the field by publishing statistical profiles of its closed investigations in its Annual Reports. Earlier this year ORI published a 5-year summary containing descriptive statistics on 150 investigations closed from 1993-97. ORI has also supported studies of whistleblowers and respondents. Using data from its Annual Report on Possible Research Misconduct, ORI has shown how often misconduct allegations are being received by institutions, what

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ORI Seeks Comment On Guidelines for Editors

ORI is seeking comment on guidelines it has developed to assist journal editors to report suspect manuscripts, facilitate misconduct investigations, improve the correction of the literature, and promote research integrity.

The guidelines are posted on the ORI website at http://ori.dhhs.gov. **Comments are due August 1, 1999.**

The guidelines suggest that editors first determine the funding source for the research. ORI offers assistance in identifying misconduct officials at funding agencies or institutions to whom queries may be addressed.

If PHS funding is involved, ORI would help to determine whether the alleged misconduct falls under the PHS definition, provide the name of the responsible official at the awardee institution, or refer the case to the institution for the journal editor.

The guidelines also indicate that ORI seeks the assistance of journal editors in investigating some allegations. ORI may ask for original manuscripts, illustrations, correspondence, reviews, and computer-generated data. Occasionally, ORI may ask for the assistance of a reviewer.

To ensure that editors are aware of misconduct in published articles, ORI sends editors the *Federal Register* notice of a finding of misconduct, the ORI

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What's Inside

Dismissal of Civil Suit by Dr. Popovic Affirmed

On April 20, 1999, a panel of the U.S. Court of Appeals for the Fourth Circuit affirmed the district court's dismissal (D.Md.) of a civil suit brought by a former NIH scientist, Mikulas Popovic, M.D., Ph.D. See *Popovic* v. *United States of America, et al.*, No. 98-1432 (4th Cir.). Dr. Popovic raised claims of negligent investigation and invasion of privacy relating to the scientific misconduct investigation conducted by the former Office of Scientific Integrity (OSI) and ORI's review of the matter. He also alleged that the OSI/ORI scientific misconduct investigation was not conducted fairly and that NIH's refusal to rehire him during the pendency of the investigation violated public policy.

The 4th Circuit affirmed the dismissal of Dr. Popovic's claims for negligent investigation and invasion of privacy because they essentially "arise out of" a claim of defamation, which is barred under the Federal Tort Claims Act (FTCA). The Court also rejected Dr. Popovic's due process claims about the fairness of the OSI/ORI investigation because they are really constitutional claims, which are also barred under the FTCA. Finally, the Court also rejected Dr. Popovic's refusal to rehire claim because there is no established general policy under Maryland state law that an individual must be hired merely because he has the requisite professional qualifications.

Research Agenda

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types of institutions are reporting misconduct allegations, and where misconduct is occurring.

ORI is considering commissioning papers on significant topics and organizing a research conference to further stimulate the field. Comments and suggestions on the ORI research agenda should be addressed to Dr. Mary D. Scheetz, Division of Policy and Education, ORI. Phone: 301-443-5300. Fax: 301-443-5351. E-mail: mscheetz@osophs.dhhs.gov.

Chinese Scientists Address Misconduct

China joined the parade of nations beginning to address scientific misconduct in February when a national meeting of journal editors and scientific society officers, organized by the China Association for Science and Technology, adopted a code of conduct designed to reduce the incidence of plagiarism, fabrication and other acts of misconduct by Chinese scientists, according to *Science*.

The seven-part "Moral Convention" suggests "that authors found to have committed plagiarism, fabrication, or falsification of data be warned in writing, followed by a boycott of future articles, notification of their home institution, and public disclosure of their misdeeds," *Science* reported. A former journal officer said, "There must be no compromise over dishonesty and no cover-up. Taking pity will harm the cause of science."

Some scientists feel adoption of the code of conduct will not be sufficient to root out the problem, according to *Science*. Others "fear that self-interest may stifle efforts to root out misconduct" unless a broad national policy is developed to address the problem.

Editorial Policies Suggested

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report or Voluntary Agreement, and, if applicable, the decision of the Departmental Appeals Board. The guidelines urge editors to publish corrections or retractions resulting from scientific misconduct cases.

The guidelines further suggest some editorial policies that journals could adopt to promote research integrity including publishing a notice informing contributors that suspect manuscripts will be appropriately pursued, developing procedures for handling suspect manuscripts, requiring co-author signatures, informing contributors that their data may be requested during the review process or after publication of the article, creating guidelines for reviewers, and adopting a correction/retraction policy.

Tips for Handling Physical Evidence in Scientific Misconduct Cases

This is the second of two articles on the importance of evidence management in misconduct cases. The first article, "Tips for Sequestration of Physical Evidence in Scientific Misconduct Cases" appeared in the December 1998 *ORI Newsletter*. These articles are intended to provide suggestions on the sequestration of data that will be useful to institutions conducting misconduct inquiries and investigations.

As indicated in the earlier article, if evidence is not sequestered systematically or promptly, with an identifiable chain of custody, the integrity of the evidence can be questioned, creating avoidable complications in misconduct cases. Attention to detail is vital and it is better to secure more, rather than less, evidence and corroborating information. Proper evidence management protects the research and all those involved.

This article covers the completion of the sequestration of physical evidence, and the post-sequestration phase.

After collecting the evidence, place it in secure site(s), check it immediately against the custody forms, and arrange for access to the evidence only under close supervision, so the evidence is not altered in any way.

Have knowledgeable staff prepare a more detailed inventory of the most pertinent items.

Ask the respondent to suggest what evidence may be essential for the continued functioning of the research unit. Decide how and when copies or samples of this material can be provided for the ongoing research.

Arrange for the committee, respondent, and appropriate witnesses to have access to the detailed inventory and copies of pertinent evidence.

Arrange for preparation of clear "working copies" of the most important evidence. The working copies are conforming copies, which include all elements on the sheet from margin to margin, any covered elements, and with the reverse checked and copied if informative. On the "master copy," add investigative labels for each notebook, folder, chart, etc., and add numbers to each page along with annotations of any relevant observations, such as whether an item is original handwriting or a photocopy. Provide working copies to the committee, respondent, experts, and portions as appropriate to witnesses to ensure accurate and easy communication about the evidence and to reduce handling of the original evidence. As the committee organizes the issues and new items of evidence become relevant to the investigation, continue to make working copies.

During the inquiry and investigation processes, use the working copies whenever possible. During interviews, ORI usually has the original evidence available, but, whenever possible, uses the working copies to identify exhibits, point out features, etc. The original evidence is handled at all times by a designated custodian, who confirms the exhibit cites.

As the investigation proceeds, develop the collateral and comparison evidence in the same manner.

Make provision for analyses of the evidence under custody. Routine analyses include a detailed inventory of the various locations of experimental records linked to each questioned claim as explained below. A time line of events is very helpful in understanding the availability of experimental factors, etc. Forensic document and biological analyses may be conducted by experts, and expert statistical analyses are frequently very helpful.

Develop all evidence from computers. Use an expert to secure the information from computer CPUs or physically secure the CPUs directly. Check for and

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Proposed AAUP Policy Obligates Faculty to Pursue Misconduct

Faculty have a duty to pursue what they believe to be well-founded concerns of professional wrongdoing by their colleagues and that obligation is not diminished by the potential risks involved, according to a statement being considered for adoption by the American Association of University Professors (AAUP).

The proposed statement, "On the Duty of Faculty Members to Speak Out on Misconduct," rests this obligation on the AAUP 1940 *Statement of Principles on Academic Freedom and Tenure* and the responsibilities of members of a profession to "promote adherence to norms essential to maintaining the integrity and autonomy of the profession."

According to the *Statement of Principles*, institutions of higher education "are conducted for the common good and not to further the interest of either the individual teacher or the institution as a whole." The proposed statement asserts "the common good is best served when members of the academic community effectively regulate their own affairs, which they do when they act ethically themselves and also when they seek to ensure such action by others."

As members of a profession, the proposed statement declares faculty members "should guard their own standards of professional behavior. To guard is to call attention to abuses of those standards, for in speaking out professors exercise their duty, as members of a self-regulating community, to deal with unethical conduct of a member of the community."

Call for Educational Links

ORI is expanding the resources on its web site. Do you have educational material to add as a hot link?

Contact Dr. Alicia Dustira at 301-443-5300; Fax 301-443-5351; E-mail: adustira@osophs.dhhs.gov.

ORI's web site is http://ori.dhhs.gov.

CASE SUMMARIES

Ms. Maria Diaz, Rush-Presbyterian-St. Luke's Medical Center (RPMC): ORI found that Ms. Diaz, former data manager for two multicenter cancer prevention clinical trials at RPMC, engaged in scientific misconduct in clinical research supported by NCI cooperative agreements. Ms. Diaz intentionally falsified and/or fabricated research data and information collected at RPMC for the Breast Cancer Prevention Trial (BCPT) under the National Surgical Adjuvant Breast and Bowel Project and a secondary prevention trial for lung cancer sponsored by the M.D. Anderson Cancer Center and Eastern Cooperative Oncology Group. Ms. Diaz falsified data related to entry criteria and treatment compliance on the secondary lung cancer prevention trial. She fabricated reports of follow-up examinations for subjects entered on the BCPT, falsified laboratory test results, and forged signatures of physicians on informed consent documents. For 3 years beginning March 13, 1999, Ms. Diaz is prohibited from serving in any advisory capacity to PHS, and her participation in PHS-funded research is subject to supervision requirements.

Chang-Fen Huang, Ph.D., State University of New York at Stony Brook (SUNY-SB): ORI found that Dr. Huang, former graduate student, Department of Biochemistry, SUNY-SB, engaged in scientific misconduct in reporting and conducting research supported by an NINDS grant. ORI found that Dr. Huang falsely mislabeled and relabeled six autoradiographs that she had obtained from earlier unrelated experiments to make them appear to have come from several different and separate experiments. Dr. Huang then used these falsified data as figures in her dissertation and in a publication (C.F. Huang, et al. "Depolarization-transcription signals in skeletal muscle use calcium flux through L channels, but bypass the sarcoplasmic reticulum." *Neuron* 13:167-177, 1994.). It was retracted at *Neuron* 13(1):1294, 1998. Dr. Huang accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning April 20, 1999, to exclude herself from Federal grant, contract, or cooperative agreements and from serving in any advisory capacity to PHS.

Journal Has Extensive Procedures For Responding to Inappropriate Acts

A journal has established extensive procedures for responding to "specific inappropriate acts in the publication process" that includes the conduct of an inquiry and investigation and the imposition of sanctions.

The *American Journal of Obstetrics and Gynecology*, published by Mosby, Inc., includes but does not limit "inappropriate acts" to the following: fabrication, falsification, plagiarism, repetitive publication, violations of Federal, State, or institutional rules of research involving human subjects, experimental animals, DNA, new drugs, and new devices or radioactive materials, failure to retain all the primary data and tissue, gift or honorary authorship, and conflicts of interest.

If an inquiry proceeds to an investigation, the editor becomes the accuser and, if sued, is defended and indemnified by the publisher. An effort is made to protect the original accuser's anonymity.

The accused is notified of the allegation and his or her rights to counsel, call and cross-examine witnesses, and present and examine evidence. Notification of the investigation is sent to officials in the department, medical school, hospital, and university of the accused.

A letter of exoneration is sent to appropriate officials when no inappropriate acts are found. When inappropriate acts are found, notice is sent to all parties notified of the investigation and the National Library of Medicine. The sanctions range from a letter of reprimand to a prohibition on the submission of a manuscript for 2 years to life. Retractions are published on a prominent page at the request of the respondent, the institution, or the editor. The policy is published in each January issue.

On-Site Technical Assistance Available From ORI

Call 301-443-5330

Journal Issue Addresses Scientific Misconduct

In April, *Science and Engineering Ethics* (*SEE*) published a special issue that draws together a major collection of papers and commentaries reviewing much of the history of the controversial subject of scientific misconduct in the United States. Contributions document differing approaches to handling misconduct issues, examine the complexity of developing a single government-wide definition, and predict concerns that will affect the scientific community in the future.

Authors include scientists, ethics scholars, lawyers, and policy specialists from ORI, the Office of Science and Technology Policy, the National Science Foundation, National Academy of Sciences, and leading academic institutions. The articles and accompanying commentaries edited by Stephanie Bird and Alicia Dustira present and extend perspectives shared by participants in a special symposium held during the 1998 Annual Meeting of the American Association for the Advancement of Science entitled "Misconduct in Science: A Decade of Progress or Merely Years of Controversy?" and organized by Dr. Dustira and Barbara Mishkin.

Featured papers are "Changing Explanatory Frameworks in the U.S. Government's Attempt to Define Misconduct" by David Guston; "Confronting Misconduct in Science in the 1980s and 1990s" by Nicholas Steneck; "Ambiguity, Trust, and the Responsible Conduct of Research" by Frederick Grinnell; "The Fallout: What Happens to Whistleblowers and Those Accused but Exonerated of Scientific Misconduct?" by James Lubalin and Jennifer Matheson; "Developing a Federal Policy on Research Misconduct by Sybil Francis; "The History and Future of ORI" by Chris B. Pascal; and "Scientific Misconduct: Present Problems and Future Trends" by Barbara Mishkin.

This special issue also complements a previous special issue of *SEE*, "Whistleblowing and the Scientific Community."

Complete content lists and order forms are available at the web site http://www.cableol.co.uk/opragen.

Acting Heads Named For Two ORI Units

Acting heads have been named for the Division of Research Investigations (DRI) and the Research Integrity Branch, Office of the General Counsel (OGC), because of the retirement of Dorothy K. Macfarlane, M.D., and the departure of Marcus H. Christ, Jr., respectively.

Alan R. Price, Ph.D., Chief, Investigations Branch A, was appointed Acting Director, DRI, and Gail L. Gibbons, Deputy Chief, was named Acting Chief Counsel.

Dr. Macfarlane, who retired May 1, served twice as Acting Director, DRI, during her 7 years in ORI. Her latest stint began in March 1996 when Chris B. Pascal was named Acting Director, ORI. Dr. Macfarlane served as Acting Director, DRI, for 19 months before becoming Deputy Director, DRI, in February 1995.

A Commissioned Officer in the U.S. Public Health Service, Dr. Macfarlane joined the former Office of Scientific Integrity (OSI) in February 1992 as Senior Medical Officer and continued in that position when ORI was created. She worked for the National Cancer Institute for 15 years before joining OSI.

Mr. Christ has headed the Research Integrity Branch, OGC, since February 1995, initially as Acting Chief and then as Chief. Prior to his arrival at ORI in 1992, he was a litigator for the Health Care Financing Division (HCF), OGC. In May, he returned to HCF in Baltimore to serve as a Supervisory Trial Attorney for Medicare and Medicaid litigation.

Alan R. Price served as Chief, Investigations Branch A, since 1992. Prior to joining OSI in 1989 where he was a senior scientist and assistant director, Dr. Price worked as the AIDS Unit Assurance Coordinator in the Office for Protection from Research Risks and as a program officer for genetics in the National Institute on Aging. He served as an associate professor of biological chemistry and Assistant Dean for Research in the University of Michigan (UM) Medical School and Assistant Vice President for Research at UM before entering government service. Dr. Price

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Indices Link Evidence to Claims

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secure all system backups. Have an expert use a program to look for erased evidence.

Develop a series of indices to link important items of evidence by their label and page. One essential index is the chart which displays the location of each questioned claim (e.g., figure panel, text cite), the sample sources (animals, patients, etc.), the experimental protocols, the samples used, the raw experimental data, laboratory data summaries, and various versions of results claimed. Some institutions have found that an experienced senior scientist may be able to develop such indices and perform some of the routine analyses described earlier in preparing for the work of the committee.

Using the chart which indexes the locations of the physical evidence and the evidence labeled and paginated on working copies, it is easy to link the findings about each questioned claim to the evidence during the committee deliberations and to carry cites into the final report and any following proceedings. At ORI, we copy or scan in the pertinent evidence into the report at the appropriate place.

Retain the evidence in custody until all PHS actions are complete. ORI may request copies of the relevant evidence, if not already appended to the report, and it may be necessary to turn over custody of the original evidence to Federal officials. In that case, the custodian should be prepared with custody documentation and testimony.

When notified of completion of the final PHS action, return the evidence to the proper individual and obtain a receipt for its return.

ORI Annual Report - 1998

Coming in September

Houston Conference Focusses on Research Integrity

ORI and six Texas research institutions co-sponsored a conference on March 11-12, 1999, on "Research Integrity: A Professional, Ethical, and Social Obligation" that drew 143 participants to Houston.

Dr. Stanley Reiser from the University of Texas-Houston gave the keynote address, tracing the historical roots of the development of ethics in science. Dr. Ruth Bulger from the Uniformed Services University of Health Sciences gave specific examples of ways to ensure objectivity in research.

A panel of scientists, including Dr. Alan Price, ORI, talked about issues in the ethics of authorship and publication. They discussed the difficulties of dealing with possible misconduct in science when conducting research and writing up the results, deciding on authorship, selecting journals, suggesting reviewers, dealing with confidentiality and integrity in the review process, and decisions editors and publishers need to make.

In a session on the ethics of randomized clinical trials, Dr. Dorothy Macfarlane described ORI's experience in handling cases involving error or misconduct on the part of physicians, nurses, and clinic data managers. Dr. Harold Vanderpool from the University of Texas Medical Branch at Galveston outlined different views of the ethics of human subjects protection.

At the end of the conference, Dr. John Grabowski from the University of Texas-Houston concluded that codification of ethical constructs has been beneficial, there is a need for cross-cultural training, rigorous inquiry and training may minimize misconduct, and all parties must work together to mitigate bias in research.

Conference proceedings are being prepared and will be distributed to all conference participants this summer. For further information, contact Dr. Sandra Hanneman, University of Texas-Houston Health Science Center, Center for Nursing Research, 1100 Holcombe Blvd., Suite #4.430, Houston, TX 77030; Phone: 713-500-2030; Fax: 713-500-2033; E-mail: shannema@son1.nur.uth.tmc.edu.

Conference Proposals Due October 1

ORI is seeking proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI in developing a conference or workshop on scientific misconduct allegations or the promotion of research integrity. The amount of funding available generally would be from $5,000 to $20,000. ORI intends to hold four to six regional conferences or workshops each year in strategic locations around the country.

October 1, 1999, is the next due date for conferences proposals. Proposal instructions are available on ORI's web site **http://ori.dhhs.gov** or by calling Dr. Alicia Dustira at 301-443-5300, email: adustira@osophs.dhhs.gov.

MEETING

July 21-25, 1999. "Graduate Research Ethics Education Workshop" in Bloomington, IN. Contact Brian Schrag, Ph.D., Association for Practical and Professional Ethics, 618 East Third St., Bloomington, IN 47405-3602; Phone: 812-855-6450; Fax: 812-855-3315; E-mail: bschrag@indiana.edu. See announcement at http://php.ucs.indiana.edu/~appe/home.html.

ORI Staff Changes

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received his doctorate in biochemistry from the University of Minnesota.

Gail L. Gibbons has been a member of the Research Integrity Branch, OGC, since 1992. Other government service included 9 years at the Interstate Commerce Commission in several positions including Chief Counsel, Office of the Chairman, and Senior Attorney, Commissioners' Offices. Ms. Gibbons also worked in a private law firm in Arizona and as a consulting attorney in Washington. She received her law degree from the University of Arizona where she was Article and Note Editor for the law review.

ORI Co-Sponsoring Conference For Research Managers

ORI is co-sponsoring a conference with Sigma Xi, The Scientific Research Society on September 10, 1999, in Albuquerque, NM, on problems faced by research managers. "Ethical Challenges and Practical Solutions for Managers in Research" will suggest practical solutions to ethical challenges facing researchers and their managers.

Contact Dr. John F. Ahearne, Director, Sigma Xi Center, Sigma Xi, 99 Alexander Dr., P.O. Box 13975, Research Triangle Park, NC 27709, Tel: 919-547-5213; Fax: 919-549-0090; E-mail: ahearne@sigmaxi.org.

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ORI NEWSLETTER

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